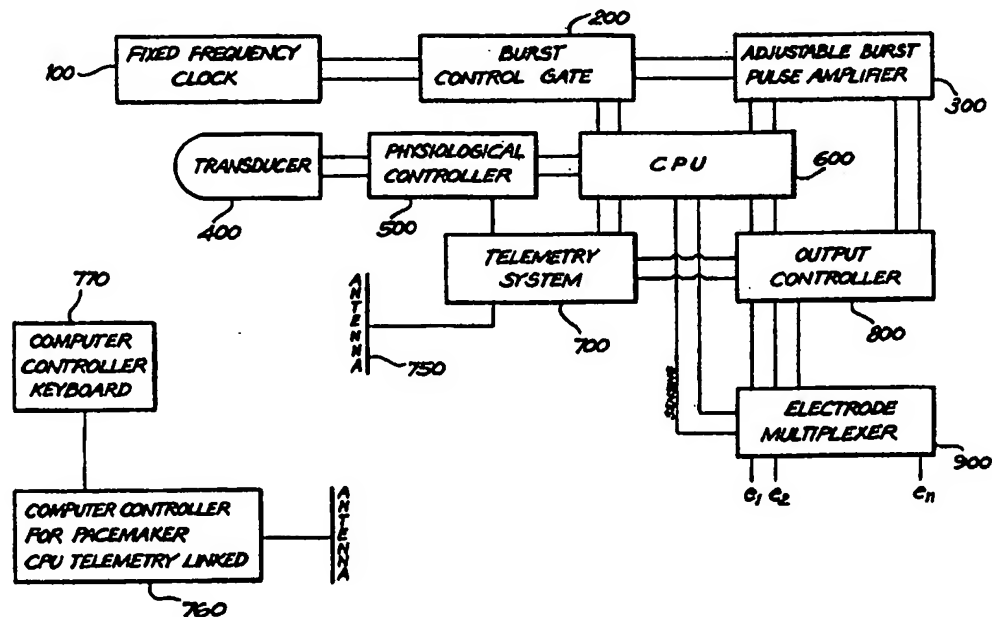




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | | |
|---|--|---|--|
| (51) International Patent Classification ⁶ : A61N 1/36 | | A1 | (11) International Publication Number: WO 99/06105 |
| | | | (43) International Publication Date: 11 February 1999 (11.02.99) |
| (21) International Application Number: PCT/AU98/00609 | | (81) Designated States: AU, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). | |
| (22) International Filing Date: 31 July 1998 (31.07.98) | | | |
| (30) Priority Data: PO 8334 31 July 1997 (31.07.97) AU | | Published With international search report. | |
| (71)(72) Applicant and Inventor: DESMOND, Noel, Gray [AU/AU]; 5 Excalibur Court, Sovereign Islands, QLD 4216 (AU). | | | |
| (74) Agent: GRIFFITH HACK; G.P.O. Box 4164, Sydney, NSW 2001 (AU). | | | |

(54) Title: IMPROVED HEART PACEMAKER



(57) Abstract

The present invention relates to a method of placing the heart into a heart pacemaker apparatus. Conventional pacemakers pace the heart by applying single electrical bolts for each heart beat required. For a heart beat of 60 beats per minute (60bpm) a pulse of 0.5 milliseconds in width is provided 60 times. This uses a significant amount of energy. In the present invention, the heart is paced by providing a burst of a plurality of sharp-rise time pulses for each heart beat. This is more energy efficient. The invention also discloses novel electrode arrays for an apically positioned pacemaker apparatus.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | | | |
|----|--------------------------|----|--|----|--|----|--------------------------|
| AL | Albania | ES | Spain | LS | Lesotho | SI | Slovenia |
| AM | Armenia | FI | Finland | LT | Lithuania | SK | Slovakia |
| AT | Austria | FR | France | LU | Luxembourg | SN | Senegal |
| AU | Australia | GA | Gabon | LV | Latvia | SZ | Swaziland |
| AZ | Azerbaijan | GB | United Kingdom | MC | Monaco | TD | Chad |
| BA | Bosnia and Herzegovina | GE | Georgia | MD | Republic of Moldova | TG | Togo |
| BB | Barbados | GH | Ghana | MG | Madagascar | TJ | Tajikistan |
| BE | Belgium | GN | Guinea | MK | The former Yugoslav Republic of Macedonia | TM | Turkmenistan |
| BF | Burkina Faso | GR | Greece | | | TR | Turkey |
| BG | Bulgaria | HU | Hungary | ML | Mali | TT | Trinidad and Tobago |
| BJ | Benin | IE | Ireland | MN | Mongolia | UA | Ukraine |
| BR | Brazil | IL | Israel | MR | Mauritania | UG | Uganda |
| BY | Belarus | IS | Iceland | MW | Malawi | US | United States of America |
| CA | Canada | IT | Italy | MX | Mexico | UZ | Uzbekistan |
| CF | Central African Republic | JP | Japan | NE | Niger | VN | Viet Nam |
| CG | Congo | KE | Kenya | NL | Netherlands | YU | Yugoslavia |
| CH | Switzerland | KG | Kyrgyzstan | NO | Norway | ZW | Zimbabwe |
| CI | Côte d'Ivoire | KP | Democratic People's Republic of Korea | NZ | New Zealand | | |
| CM | Cameroon | | | PL | Poland | | |
| CN | China | KR | Republic of Korea | PT | Portugal | | |
| CU | Cuba | KZ | Kazakhstan | RO | Romania | | |
| CZ | Czech Republic | LC | Saint Lucia | RU | Russian Federation | | |
| DE | Germany | LI | Liechtenstein | SD | Sudan | | |
| DK | Denmark | LK | Sri Lanka | SE | Sweden | | |
| EE | Estonia | LR | Liberia | SG | Singapore | | |

IMPROVED HEART PACEMAKER

The present invention relates to a method of pacing the heart and to a heart pacemaker apparatus.

Conventional existing cardiac pacemakers usually
5 constitute a pulse generator housed within a hermetically sealed metal capsule. The partly insulated metal capsule is arranged to be inserted within a patients body, normally near one of the pectoral muscles. One or two insulated leads having their proximal ends connected into a receiving
10 port of the metal capsule so as to provide a direct connection with the pulse generator, have their distal ends connected to one or more bare metal electrodes which are located inside the patients heart. Typically, such transvenous electrodes are positioned in the right
15 ventricle and/or the right atrium and deliver stimulating impulses to the endocardium to pace the heart.

Conventional pacemakers utilising transvenous electrodes suffer from a number of problems. These include:

- 20 1. Loss of synchronous mechanical contraction of the left and right ventricles. This is referred to as pacemaker induced left branch block type conduction disturbance. This is caused by the positioning of the stimulating electrode on the
25 free wall of the right ventricle;
2. The requirement for relatively long conductive leads to connect the pacemaker with the electrode means that there is relatively large impedance between the pulse generator and the electrode,
30 requiring the generation of high voltages and therefore resulting in a large drain from the power source. This shortens the life of the pacemaker and/or requires the provision of a large and bulky battery;
- 35 3. As pacing pulses are applied by the single

- 2 -

electrode, fibrous tissue tends to build up around the electrode (as the bodies reaction to foreign material and the pulsing). As the fibrous tissue build up continues, increasing stimulating voltage is required to be applied to pace the heart (the cardiologist will often adjust the pacing voltage after a number of weeks following implantation, to take account of the fibrous tissue growth). This again reduces battery life and/or requires a bulkier battery;

4. Generally only a single electrode is implanted in conventional ventricular paced pacemakers. This single electrode is used both for sensing cardiac activity and providing pacing pulses. When pulsing at higher rates, polarisation of the electrode site increases due to the reduced time between succeeding stimulating impulses thereby not permitting dispersion of the voltage of polarisation. Pacing voltage must therefore be increased to overcome the polarisation potential and apparent increase in impedance. This, again, results in an increased drain on the power source.

The implementation of long electrode leads can also cause problems at the implementation site. There have been a number of cases of leads corroding and breaking, in which case a useless electrode is left implanted and it is necessary to implant a further electrode, requiring further surgery. It is also necessary to remove the degraded lead in order to prevent health problems. A number of health problems have been experienced with degraded leads.

The applicants own earlier international patent application, number PCT/AU93/00541, discloses a pacemaker which comprises a base member arranged to be positioned about the apical area of the heart. The base member mounts

- 3 -

a number of electrodes which are arranged to abut the surface of the heart and provide electrical stimulation thereto, and also to provide a cardiac sensing function. Stimulation of the heart using a plurality of apically positioned electrodes acts to stimulate the heart in a more natural way and substantially avoids pacemaker induced left branch block type conduction disturbance. The construction of the pacemaker also enables reduction in polarisation and impedance between the pulse generator and the electrode.

5 Using a plurality of electrodes also means that electrodes can be selected for the most convenient and optimum pacing and also to deal with polarisation. Disclosure of PCT/AU93/00541 is incorporated herein by reference.

10 The present invention concerns further improvements in methods and apparatus for pacing the heart. The improvements of the present invention can be utilised with an apical-type pacemaker, such as disclosed in PCT/AU93/00541, or could, although less preferably, be utilised with a pacemaker of conventional type.

15 Prior art pacemakers pace the heart by applying a single electrical pulse for each heart beat required. If a heart beat of sixty beats per minute is required (60bpm) then a single electrical pulse is generated by the pacemaker 60 times per minute and applied to the pacemaker electrode for each required beat. The basic pulse repetition rate of most pacemakers varies between approximately 60 and 120 bpm, depending upon physiological requirements. In current pacemaking technology, this rate may be adjusted both by the operator and/or by some

20 semi-automatic in-built physiological control device to automatically adjust to the patients exercise demands. Conventionally, each pulse applied is 0.5ms in width. Such a pulse can use a relatively large amount of energy. The present applicants have found that it is not necessary to

25 provide such a pulse to effectively stimulate the heart.

30

35

- 4 -

From a first aspect, the present invention provides a method of pacing a heart, comprising the steps of, for each required paced heart beat, applying an electrical stimulus to the heart by applying a group of a plurality of
5 electrical pulses, the time of occurrence of each group in a sequence of such groups being arranged to provide the required paced heart rate.

Each single electrical pulse in a group of pulses preferably has a width which is relatively short. By
10 relatively short, we mean it is shorter than the conventional pulse applied by conventional pacemakers. Preferably each group comprises a sequential burst or wave train of pulses. The total period or width of the burst may extend to substantially the width of a conventional
15 pulse, 0.5ms, for example. The amplitude of the pulses may be the same as the amplitude of a conventional pulse.

The present applicants believe that what is important in dictating whether or not a stimulating pulse would be sufficient to stimulate a heart beat, is the rise time of
20 the pulse rather than its width. The applicants believe that a fast rise time pulse will provide sufficient impetus to the heart to cause electrical stimulation and heart beat. A plurality of such fast-rise type pulses will ensure that the heart is paced.

25 By applying a group of a plurality of electrical pulses for each pacing "event" (by which we mean each time that a heart beat is required to be paced) a considerable amount of energy can be saved over the conventional method of providing a single pulse of relatively large width.
30 Pacemaker life may be substantially extended because there is preferably much less drain on the battery. Alternatively a lighter and cheaper battery could be utilised for the same pacemaker lifetime which would facilitate a smaller and lighter pulse generator.

35 The method of this aspect of the invention can be used

- 5 -

with conventional pacemakers as well as with the pacemaker of the above referenced PCT application. Note that one problem with conventional pacemakers is the build up of fibrous tissue due to stimulation by the electrode. It is possible that this relatively low energy stimulation as proposed by this aspect of the present invention may also lead to less build up of fibrous tissue in conventional pacemakers, further obviating the need to use a large amount of energy from the pacemaker battery.

10 The present invention may also be utilised in a "demand" type pacemaker.

It is also possible that conventional pacemakers which are already implanted may be adapted to provide pacing in accordance with this aspect of the invention. Adaptation would be required to the circuitry of the pulse generator, but the electrode may remain implanted.

15 The present invention further provides a method of adapting a pacemaker, comprising the steps of adapting the pacemaker circuitry in order to enable the pacemaker to provide pacing by applying a group of a plurality of electrical pulses for each required paced heart beat, the occurrence of each group of pulses in a sequence of such groups being arranged to provide the required paced heart rate.

20 The present invention yet further provides a heart pacemaker, comprising a pulse generator means for causing an electrode to provide cardiac stimulating pulses to the heart, the pulse generator means being arranged to provide a sequence of groups of electrical pulses, a group of a plurality of electrical pulses being applied for each required paced heart beat.

25 The pacemaker disclosed in the applicants earlier patent application includes an array of disk-like electrodes on a surface of a base member and arranged to be applied to the apical area of the heart. The provision of

- 6 -

a plurality of electrodes allows the use of different electrodes for pacing and sensing functions and preferably alleviates polarisation problems.

The inventors have also developed an improved
5 electrode arrangement.

From a further aspect, the present invention provides a heart pacemaker comprising a base member mounting at least one electrode for pacing the heart and/or sensing electrical activity in the heart, and a pulse generator
10 means for causing the electrodes to provide heart stimulating pulses, wherein at least one electrode is formed as a ring on the surface of the base member.

Preferably there are a plurality of electrodes available for pacing and/or sensing, and more preferably
15 there are a plurality of electrodes formed as rings on the surface of the base member.

"Ring" includes a circular ring, a square ring or generally a ring of any shape, rectangular, polygonal, irregular etc.

20 Preferably, there are provided a plurality of concentric ring electrodes on the surface of the base member. Preferably each ring electrode is equal in area and more preferably the ring electrodes are capacitive electrodes each electrode having equal capacitance.
25 Preferably, a "indifferent" electrode is also provided on the base member.

Preferably, there is sufficient area of electrodes to contact substantially the entire apical area of the heart when the base member is in position.

30 Preferably, the surface area of the electrode substantially covers the surface area of the base member (apart from the insulting gaps obviously required between adjacent electrodes).

The provision of ring electrodes provides an increase
35 in area of each electrode compared with prior art

- 7 -

electrodes resulting in a lower impedance and preferably potentially increased electrical sensitivity when the electrode is in a sensing mode. Further, the increased capacitance of each electrode preferably provides for
5 higher peak stimulating impulse in the pulse generator stimulating mode. A further advantage of the increase in area of each electrode compared with the prior art is improved contact stability. Yet a further advantage is that the positioning of the base member (which is
10 preferably positionable around the apical area of the heart) is less critical due to the increased electrode heart contact area.

Any one, two, more or all of the electrodes may be chosen for pacing/sensing functions, thus providing
15 improved directivity and the opportunity for the cardiologist to select the most appropriate electrodes, preferably covering virtually the entire surface of the apical area of the heart, to provide the most appropriate stimulation for the patients heart. Cardiologists can
20 select electrodes in an attempt to mimic the natural pacing of the heart.

Preferably, the pacing may be by means of the "burst" type stimulation discussed above in relation to the first aspect of this invention.

25 The provision of a plurality of electrodes for covering much of the apical area of the heart preferably allows cardiologists more "directivity" (by which we mean they can select any one or all of the electrodes as appropriate to pace various areas of the heart) and
30 versatility. Electrodes may all be connected together to provide a sensing function and a pacing function, i.e., connected in parallel, or selective ones of the electrodes may be connected in parallel. All the electrodes may be connected in parallel to provide a defibrillation function,
35 if required.

- 8 -

In a further alternative embodiment, the or each ring electrode is segmented to provide a plurality of segments, each one of which can operate as a separate electrode separated by insulating material of the base member. This provides yet more directivity and choice for pacing and/or sensing operations. This type of electrode array is totally new to pacemaking technology. The provision of a base member with a plurality of electrodes in the form of segments of a plurality of band or ring electrodes is totally novel, and allows the cardiologist versatility in selection of electrodes to be used in pacing and/or sensing so that the cardiologist can select the electrodes to as far as possible mimic the natural operation of the heart.

Electrodes may be formed on the base member in a series of "strips" extending substantially from the centre or bottom of the base member towards the periphery of the base member. The strips preferably extend in a direction such that they will come into contact with vital areas of the heart required for pacing when the base member is fitted to the heart. Preferably strips of segmented electrodes are available for contacting the apical area of the right and left ventricle and other strips are provided for contacting the appropriate area to cause the septum to stiffen. A cardiac muscle stimulation wavefront may be directed first to stimulate and stiffen the septum, then substantially simultaneously to the right and the left ventricle, or biased right or left as is clinically determined by the operator and/or by the physiological requirements of the patient (where physiological control is applied over the pacemaker - see applicants earlier application referenced above).

From yet a further aspect the present invention provides a heart pacemaker comprising a base member mounting a plurality of electrodes and being arranged to fit to the apical area of the heart, the plurality of

- 9 -

electrodes extending across the surface of the base member such that electrodes are available to contact substantially the entire surface of the apical area of the heart, whereby to provide means for pacing and/or sensing electrical activity for the entire apical area of the heart.

Electrodes may be band or ring type electrodes as discussed above or segmented electrodes as discussed above.

Preferably the electrodes extend over substantially the entire surface of the base member.

From yet a further aspect the present invention provides a heart pacemaker comprising a base member mounting a plurality of electrodes and being arranged to fit to the apical area of the heart, the plurality of electrodes being arranged in a plurality of strips, each strip being arranged on the base member so as to extend and contact a portion of the apical area of the heart, each contacted portion may be paced or sensed separately.

Preferably, at least one strip contacts an area of the heart the electrical stimulation of which causes stimulation of the right ventricle, at least another strip contacts an area of the heart stimulation of which causes stimulation of the left ventricle and at least another strip contacts an area of the heart the stimulation of which causes stimulation of the septum.

Preferably the strips extend from substantially the centre of the base member out towards its periphery. An indifferent electrode is preferably provided on the base member, preferably at its centre.

The heart pacemaker of the present invention is preferably an epicardial extra-cardiac device, the electrodes contacting the surface of the heart tissue and not being implanted therein.

Features and advantages of the present invention will become apparent from the following description of embodiments thereof, by way example, with reference to the

- 10 -

accompanying drawings, in which:

Figure 1 is a bottom view of a pacemaker device in accordance with an embodiment of the present invention;

Figure 2 is a side view of the pacemaker of figure 1;

5 Figure 3 is a top view of the pacemaker of figure 1;

Figure 4 is a sectional view of a base member of the pacemaker of figure 1, illustrating the electrode structure;

Figure 5 is a diagram of the heart;

10 Figure 6 is a block diagram of the pacemaker circuitry for the pacemaker of figure 1;

Figures 7 and 7A are diagrams illustrating a pulsing sequence for a pacemaker in accordance with an embodiment of the present invention;

15 Figure 8 is a top view of an alternative embodiment of a pacemaker in accordance with the present invention, and

Figures 9A and 9B are cross sections through a base member of a pacemaker in accordance with further embodiments of the present invention showing alternative electrode structures.

20 The pacemaker shown in figures 1 to 4 is a self contained hermetically sealed unit which may be made of a resilient plastics material or a ceramic material (or any other material or materials compatible with mounting in the
25 human body for extended periods). The pacemaker according to this first embodiment is part hemispherical in shape or dish-like and comprises a base member 10 having a concave surface 11 which forms the upper part of the pacemaker. A housing member 9 has a convex surface 12 which forms the
30 lower part of the base member. The two members 9 and 10 form a sealed container which contains electronic circuitry (figure 6), comprising at least a pulse generator means, required to operate the pacemaker.

35 In operation, the base member 11 is arranged to be positioned about the apical area of the heart. Electrodes

- 11 -

20 mounted on the surface of the base member 11 contact the apical surface of the heart and are arranged to provide stimulating pulses to the apical area and/or sense electrical activity of the apical area.

5 The housing member 9 mounts sensing electrodes 15 arranged to contact the diaphragm and in operation to sense physiological activity of the patient. This is described in the applicants earlier PCT application referenced above, and the diaphragm/physiological sensing function will not
10 be described any further in the present application.

 The pacemaker is arranged to be positioned in the chest in the sternal region approximately below the sixth rib proximate the junction between the underlying intercostal muscles and the diaphragm. With the pacemaker
15 located in this position, the amount of relative movement between the heart and the diaphragm is minimised. The electrodes 15 can then be used to sense variations in the physical activity of the patient by detecting changes in depth, rate, etc., of breathing.

20 Figure 5 is a diagram illustrating major features of the heart. The reference letters on the diagram indicate the following features:

- A. superior vena cava;
- B. SA nodes;
- 25 C. AV nodes;
- D. Bundle of His;
- E. Bundle branches;
- F. Septum;
- G. Left Atrium;
- 30 H. Left Ventricle;
- I. Papillary muscle;
- J. Purkinje fibres;
- K. Apical pacemaker electrode site;
- L. Conventional pacemaker electrode site;
- 35 M. Mitral valve;

- 12 -

N. Tricuspid value.

The normal electrical pathway in the heart goes as follows:

B→C→D→E→J.

5 The pacemaker in accordance with this embodiment is arranged to be positioned at site K, at the apical area of the heart where the free walls of the left and right ventricles meet the ventricular septum. The pacemaker is therefore positioned so that the electrodes contact the
10 apical surface of the heart and the electrodes 15, 8 contact the diaphragm. Note that the surface of the base member 11 (figure 3) also mounts an indifferent electrode 21.

 Electrodes 20 are in the form of concentric rings.
15 The arrangement is such that electrodes 20, 21 substantially contact the entire surface of the apical area of the heart.

 The provision of electrodes substantially about the apical area, therefore, covering substantially the surface
20 area of the apical area (in this case the entire surface area of the base member 11 of the pacemaker - apart from, of course, insulating areas 22) enables any part of the area of the apex of the heart to be selectively stimulated as desired by the cardiologist. The pacemaker circuitry
25 preferably includes telemetry circuitry so that, after insertion of the pacemaker, the cardiologist may select the most appropriate electrodes for pacing the heart and the most appropriate electrodes 20 for sensing electrical activity of the heart. Preferably, in operation, pacing
30 and sensing electrodes will be separate to avoid problems with polarisation. During the lifetime of the pacemaker, the cardiologist can change which electrodes are used for pacing and/or sensing, to provide the most clinically appropriate stimulation.

- 13 -

Yet a further alternative is to have the electrodes 20 used sequentially, i.e., one pulse applied to one electrode, the next pulse being applied to another electrode, etc. In some circumstances this may be
5 advantageous.

Yet a further possibility of this electrode arrangement is that all electrodes could be selectively connected together in parallel to provide a defibrillation function, as and when required.

10 As can be seen from figure 4, which shows a cross section through the base member 11, the electrodes 21 and 20 are capacitive electrodes, and comprise capacitors C1 through C7. Capacitive electrodes were described in the applicants earlier application. A pulse applied to a plate
15 on the underside of the base member 11 will be transmitted capacitively to the electrode 20 on the surface of the base member 11. It is believed that the provision of concentric ring capacitive electrodes gives the following advantages:

A. Increase in area and capacitance compared with
20 the earlier capacitive electrodes described in the applicants earlier application, resulting in a lower impedance (capacitive reactance) and hence potentially increased electrical sensitivity, in a sensing mode.

B. Increased capacitance of each electrode providing
25 for higher peak stimulating impulse in the pulse generator stimulating mode.

C. Increase in the area of each electrode in contact with the heart resulting in possibly improved contact stability.

30 D. Less critical sensing and stimulating positioning due to increased electrode heart contact area.

E. An increase in the mechanical strength of the base member, because of the capacitive structure and the ring structure of the electrodes.

35 Several electrodes may be connected in parallel for

- 14 -

the sensing function as well as in parallel for a stimulating function.

Figure 8 shows a top view of an alternative embodiment of the pacemaker. The base member 11 of this alternative
5 embodiment mounts a plurality of electrodes 30 which are arranged in "strips" 31 which extend from the central indifferent electrode 32 to the periphery of the base member 11. It can in fact be seen that the electrodes 30
10 in each strip 31 can be considered as being segments of the concentric electrodes 20 of the embodiment of figure 3, the strips 31 being spaced from each other by insulating areas 33 of the base member 11.

This arrangement provides many electrodes, each or any of which may be selected by the cardiologist for sensing
15 and/or pacing functions. The arrangement is such that the strips 31 extend about the apical area of the heart, so that electrodes can be selected to mimic the hearts "natural" pacing. In the embodiments shown, strips 31 are arranged to contact the apical area of the right ventricle
20 (R), the apical area of the left ventricle (L) and the apical area closest to the septum (S). Electrodes in these strips can be selected for providing the most clinically appropriate pacing of the left and right ventricles and the septum. Some or all of the electrodes may be connected in
25 parallel. If clinically appropriate, however, just a single electrode may be used for pacing. The arrangement is not limited to all the electrodes being used, but merely provides an arrangement from which the cardiologist can select the most clinically appropriate pacing/sensing
30 electrode (S). The electrodes other than the R, S and L electrodes may be used for sensing only, although, as discussed above, the arrangement is not limited to this operation.

In the illustrated example the strips or segments lie
35 on axes which are separated from each other by fifteen

- 15 -

degree angles, making a total of 72 active electrodes, any combination of which may be used for pacing a heart or detecting the electrical activity of a heart.

By selectively interconnecting the electrodes in
5 clinically desirable groups, it will be evident that a cardiac muscle stimulation wave front may be directed first to stimulate and stiffen the septum, thereby improving pump function or cardiac output then substantially
10 simultaneously to the right and left ventricles, or biased right and left as is clinically determined by the cardiologist and/or by the physiological requirements of the patient (fed back via in built physiological control of the pacemaker).

Stimulation may be by the electrodes connected in
15 parallel or sequentially and the actual selection of the electrodes is dependent upon the patients clinical condition and the treatment selected by his or her clinician.

Note that the electrodes could be of different shapes,
20 i.e., disk shape, square triangular, etc., and could be of different numbers. The numbers and shape are not critical.

In the figure 8 embodiment, strips of electrodes are distributed evenly about the surface of the base member. As an alternative, the strips may be distributed unevenly
25 e.g., strips for the right ventricular area, the left ventricular area (in the apical area) and the septum. No other strips would be provided in such an embodiment.

In pacing with a conventional pacemaker, a single 0.5ms stimulating impulse is generally applied to an
30 electrode, recurring at a pulse repetition rate (PRR) of usually between 60 to 120 beats per minute, depending upon the clinical and physiological requirements of the patient. As discussed in the preamble, this conventional single pulse method uses a significant amount of energy, and leads
35 to a shorter pacemaker life and/or the requirement for a

- 16 -

larger pacemaker.

Figures 7 and 7A illustrate a pacing method in accordance with an embodiment of the present invention. The present applicants have found that it is not necessary to provide a single, 0.5ms width pulse to cause the heart to beat. Instead, it is possible to effectively stimulate the heart by providing a group of pulses of relatively short width (shorter than the conventional pulse applied by conventional pacemakers) in a sequential burst or wave train of pulses. A total period or width of the burst may extend to substantially the width of a conventional pulse, e.g., 0.5ms. The amplitude of the pulses may be the same as the amplitude of a conventional pulse.

In figure 7, for each "conventional pulse" there is in this embodiment of the present invention provided a group of six narrower pulses, each having a sequential pulse width (SPW) of t_4 . The period of each wave train pulse is t_1 . The width of the entire wave train (SWW) t_3 and will generally be set at the same level as a conventional pulse (which may or may not be 0.5ms, but will probably be there or there about - although not limited to). Each burst of pulses will be separated by a period t_5 , which may vary depending upon the physiological requirements of the paced heart. t_5 is known as the "quiescent" or "listening period" (QP). The pulse repetition period PRP is given by t_2 , which again may vary depending upon the physiological requirements and clinical requirements of the patient.

Burst or wave-train pulsing as illustrated can be applied to a conventional pacemaker or generally to any pacemaker, including the pacemaker described in relation to figures 1 to 4, 6 and 8.

In this example the pulse width of each of the t_4 narrow pulses is $10\mu s$, and six pulses are provided per burst, over the same t_3 time period of 0.5ms ($500\mu s$) six pulses will be provided. The applicants believe that a

- 17 -

sequential wave train of six pulses will be able to effectively stimulate a heart. It will be appreciated that different numbers of pulses and different pulse and burst width parameters may be employed.

5 Pulsing in this way would save considerable energy. In this example it would use only 12 percent of the energy compared to a conventional device using a single 0.5ms pulse. In other words, the battery life would be extended eight times, all other things being equal. In other words
10 the same pacemaker implant life could be attained by using a smaller lighter and cheaper battery or the pacemaker would last longer using its present battery. A smaller battery would enable a smaller and lighter pulse generator to be assembled. Clinical analysis of various pulse times
15 and intervals may be of value in a detailed study of a patients cardiac condition and useful as an aid to diagnosis.

Figure 6 is a block diagram showing the components of a pulse generator mounted in a pacemaker in accordance with
20 figure 1 through 4 or figure 8, and being arranged to provide a pulsing sequence in accordance with figure 7. The relatively narrow pulses are generated by a fixed frequency clock (or asymmetric multivibrator) 100. The frequency chosen in the figure 7 example is 6kc but if it
25 were 12kc then there would be 12 pulses in each 0.5ms burst. The frequency may also be variable within pre-determined limits so as to provide more or less t_4 sequential pulses in each t_3 burst. The pulses are fed to a burst control gate 200 where the PRR (pulse repetition
30 rate) is set to time period t_2 and wherein the pulses are counted into predetermined burst lengths and then amplified in the adjustable burst pulse amplifier 300. The output EP of the adjustable burst pulse amplifier is set by the cardiologist at implant via the central processing unit
35 (CPU 600). An output controller 800 and an electrode

multiplexer 900 provide the pulses to selected electrodes e1 through en (equivalent to electrodes 20 in figure 3 and electrodes 30 in figure 8). The CPU 600 controls the output controller 800 in accordance with clinical requirements and/or physiological inputs to select the electrodes to be used for pacing and sensing. The CPU600 and clock 100 are desirably fully year 2000 compliant. A telemetry system 700 enables a cardiologist to vary the operating parameters via the CPU 600 and output controller 800. Note that the transducer 400 may be connected to electrodes 15 of figure 1, which detect variations in the rate of movement of the diaphragm.

The telemetry system 700 includes an antenna 750 for communicating with a telemetry controller 760 (outside the patients body) operated by the cardiologist via a keyboard 770.

The electrodes which have been described in relation to previous embodiments are capacitive electrodes, which are preferred. Figs. 9A and 9B illustrate alternative electrode structures.

Figs. 9A and 9B illustrate alternative "plated through" electrodes which could be used instead of the capacitive electrodes. Lead through electrodes would enable an increase in current flow, for defibrillation for example.

With reference to Fig. 9B, reference numeral 1 discloses a lead through electrode of conductive material, reference numeral 2 is an insulated base member such as the base member 11 of Figs. 8 and 4. Reference numeral 4 indicates a non-corrosive joining material, such as silver, gold or platinum.

In the embodiment of Fig. 9A, reference numeral 1 is again a lead through electrode. Reference numeral 3, however, indicates a conductive base member. Reference numeral 6 indicates an inert insulating membrane such as

silicone. A plurality of electrodes could therefore be formed from the conductive base member together with "windows" in the silicone and a plurality of conductive lead through electrodes 1.

5 Many of the features of the pacemaker described above can be used for a "demand" type pacemaker, as well as for a conventional pacemaker.

10 It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

- 20 -

CLAIMS:-

1. A method of pacing a heart, comprising the steps of, for each required paced heart beat, applying an electrical stimulus to the heart by applying a group of a plurality of electrical pulses, the time of occurrence of each group in a sequence of such groups being arranged to provide the required paced heart rate.

2. A method in accordance with claim 1, wherein each single electrical pulse in a group of pulses has a relatively short width and a relatively fast rise time.

3. A method in accordance with claim 2, wherein the width of each electrical pulse is substantially shorter than the width of a conventional pacing pulse.

4. A heart pacemaker, comprising a pulse generator means for causing an electrode to provide cardiac stimulating pulses to the heart, the pulse generator means being arranged to provide a sequence of groups of electrical pulses, a group of a plurality of electrical pulses being applied for each required paced heart beat.

5. A heart pacemaker in accordance with claim 4, wherein each electrical pulse of the plurality of pulses has a relatively short width.

6. A heart pacemaker in accordance with claim 5, wherein the width of each electrical pulse is substantially less than that of a conventional pacing pulse.

7. A method of adapting a pacemaker, comprising the steps of adapting pacemaker circuitry in order to enable the pacemaker to provide pacing by applying a group of a plurality of electrical pulses for each required paced heart beat, the occurrence of each group of pulses in a sequence of such groups being arranged to provide the required paced heart rate.

8. A heart pacemaker comprising a base member mounting at least one electrode for pacing the heart and/or sensing electrical activity in the heart, and a pulse

- 21 -

generator means for causing the electrode to provide heart stimulating pulses, wherein at least one electrode is formed as a ring on the surface of the base member.

9. A heart pacemaker in accordance with claim 8,
5 mounting a plurality of concentric ring electrodes.

10. A heart pacemaker in accordance with claim 8 or claim 9, a sufficient electrode surface area being available to contact substantially the entire apical surface area of the heart, whereby to provide means for
10 pacing and/or sensing electrical activity for the entire apical area of the heart.

11. A heart pacemaker in accordance with any one of claims 8 to 10, wherein the electrodes are capacitive electrodes.

15 12. A heart pacemaker in accordance with any one of claims 8 to 11, wherein the ring electrode is segmented to provide a plurality of segment electrodes on the base member.

13. A heart pacemaker comprising a base member
20 mounting a plurality of electrodes and being arranged to fit to the apical area of the heart, the plurality of electrodes extending across the surface of the base member such that electrodes are available to contact substantially the entire surface of the apical area of the heart, whereby
25 to provide means for pacing and/or sensing electrical activity for the entire apical area of the heart.

15. A heart pacemaker in accordance with claim 14, wherein the plurality strips containing a plurality of electrodes formed on the surface of the base member.

- 22 -

15. A heart pacemaker comprising a base member mounting a plurality of electrodes and being arranged to fit to the apical area of the heart, the plurality of electrodes being arranged in a plurality of strips, each
- 5 strip being arranged on the base member so as to extend and contact a portion of the apical area of the heart so that each contacted portion may be paced or sensed separately.

1/6

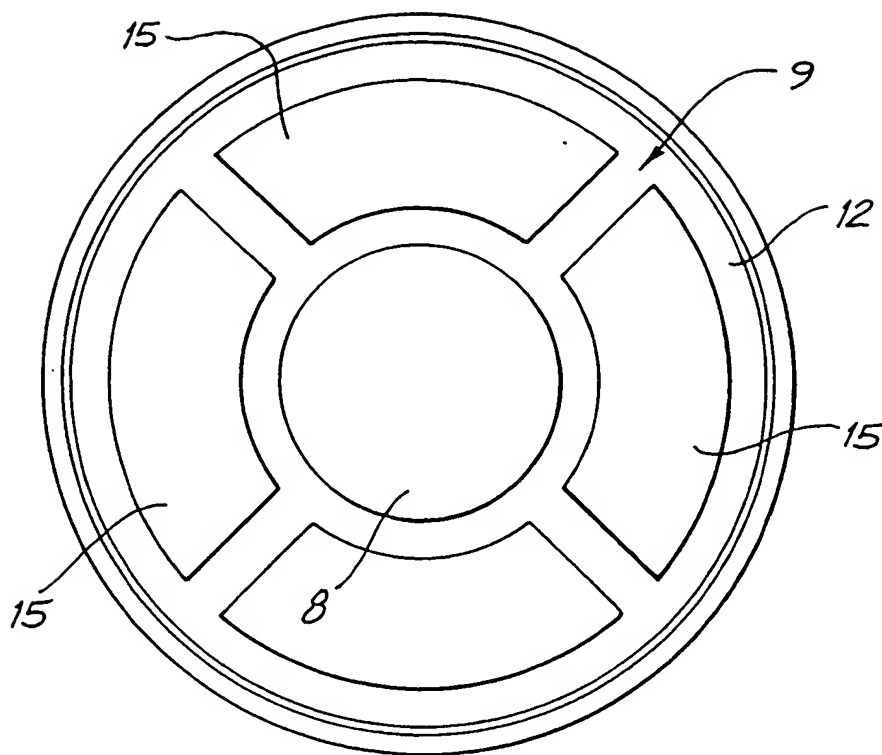


FIG. 1

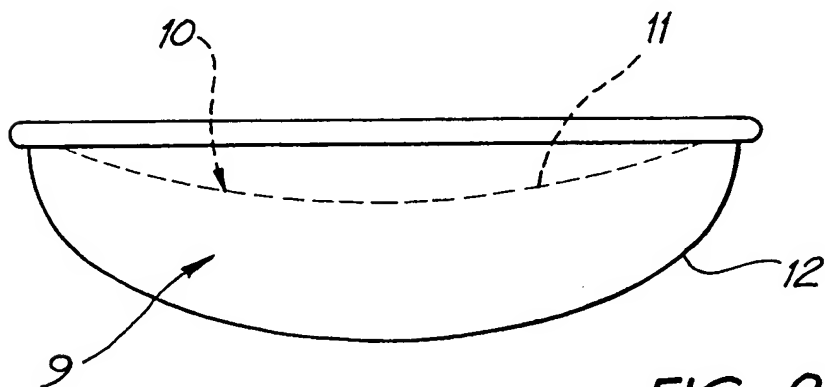


FIG. 2

2/6

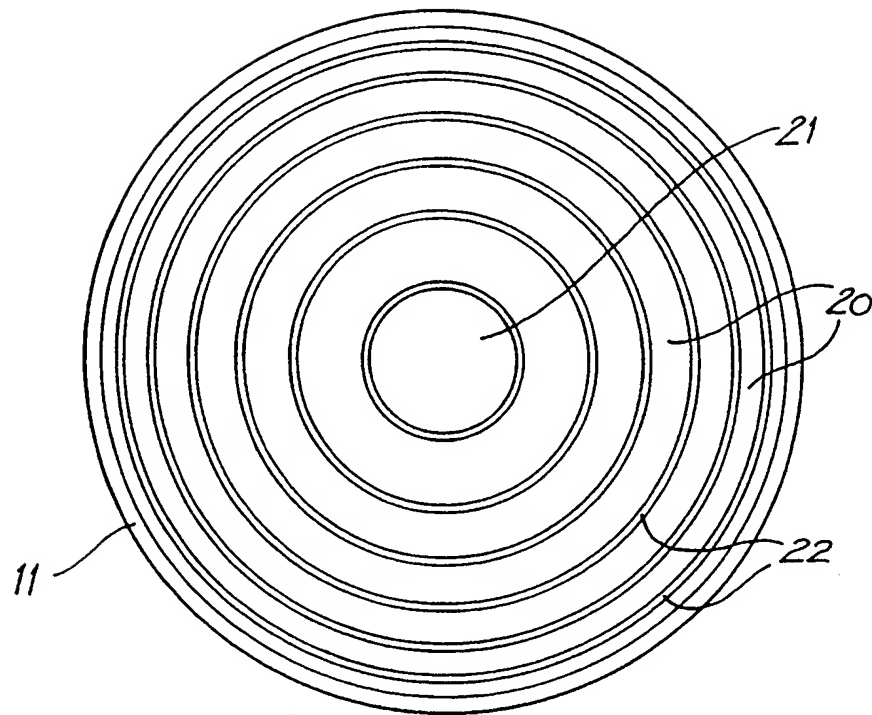


FIG. 3

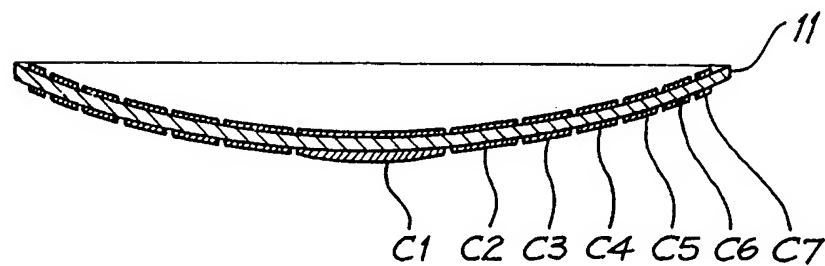


FIG. 4

3/6

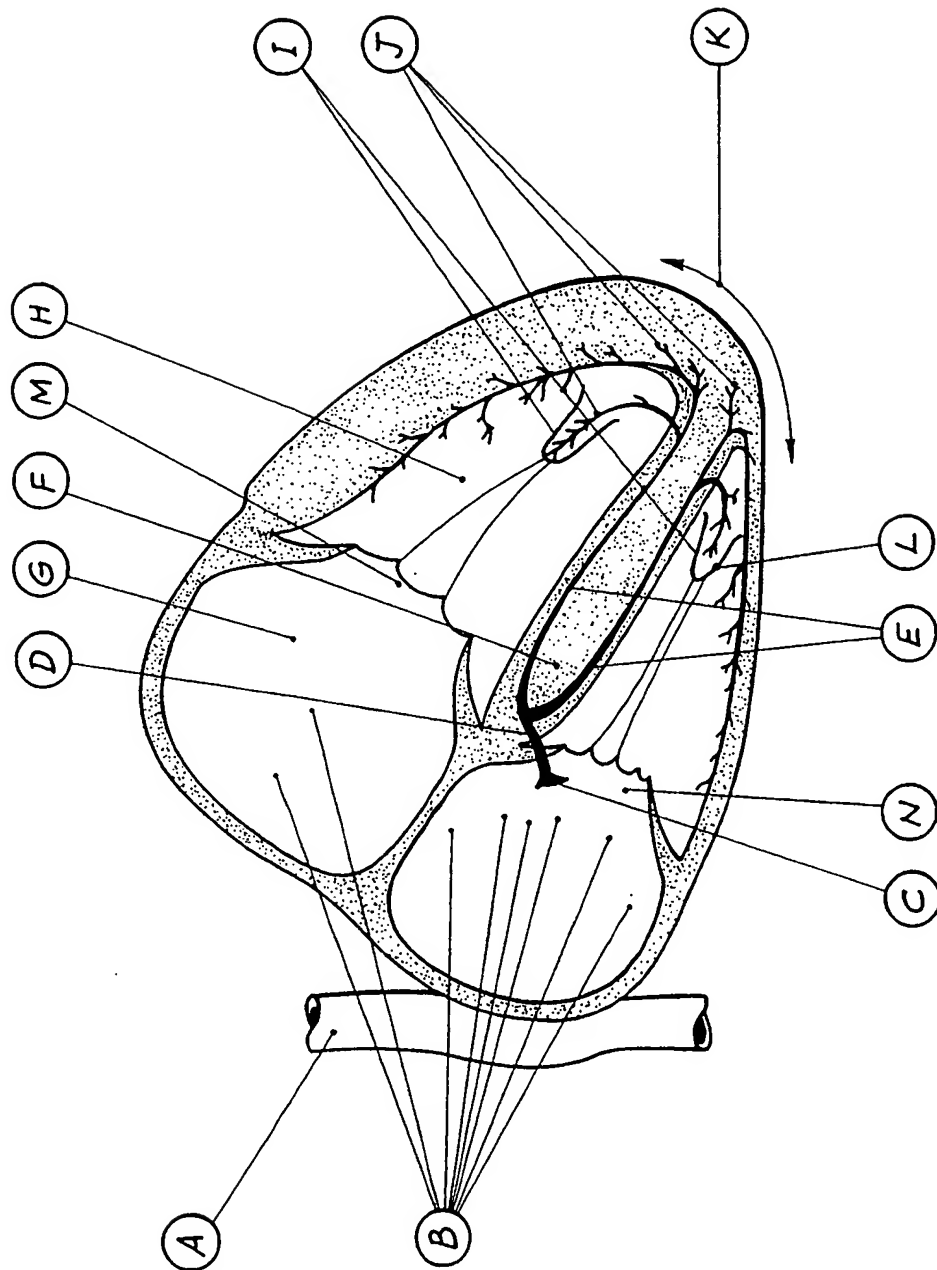


FIG. 5

4/6

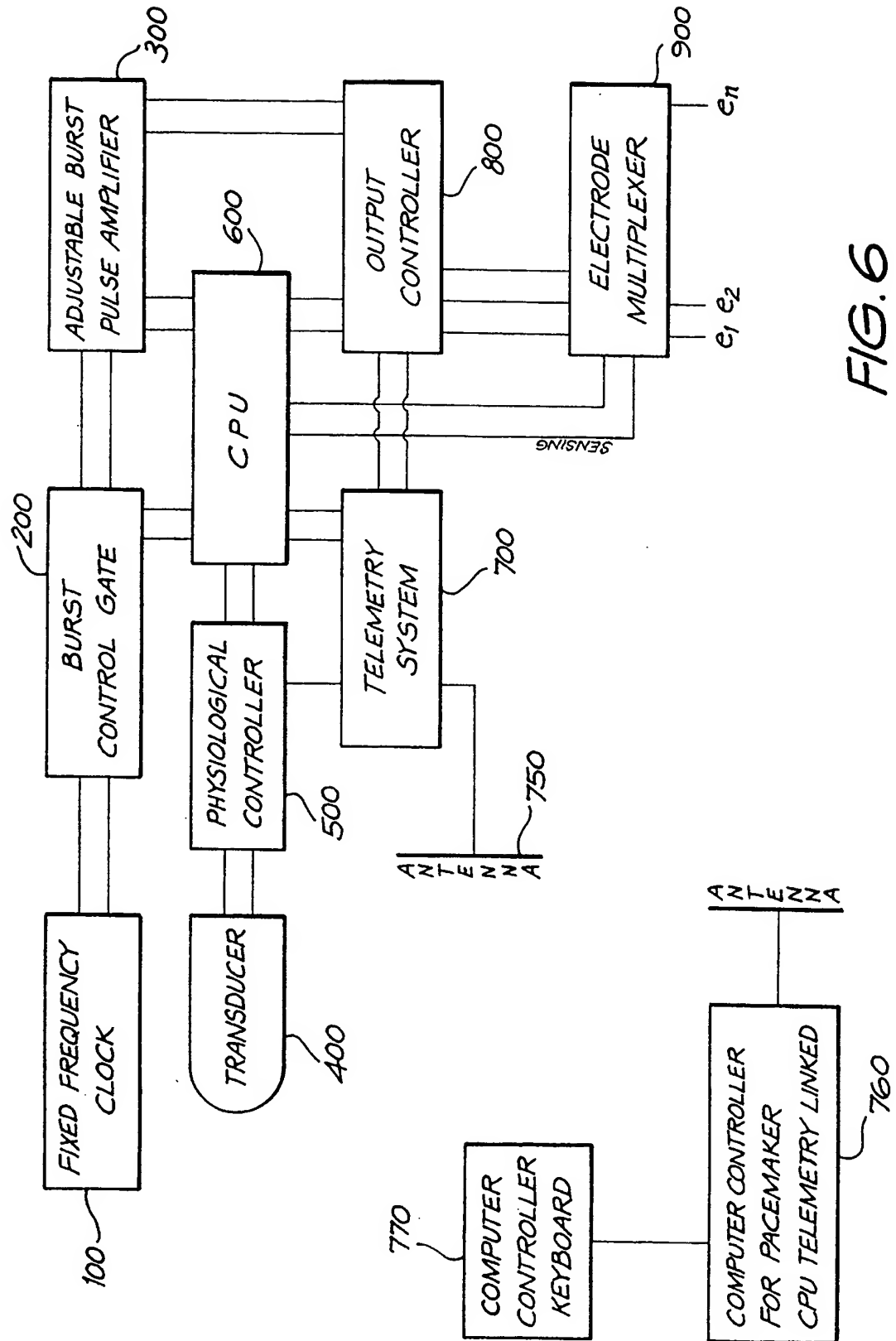


FIG. 6

SEQUENTIAL PULSE SEPARATION TIME (SPS) _____ t_1
PULSE REPETITION PERIOD (PRP) _____ t_2
SEQUENTIAL WAVE-TRAIN WIDTH (SWIN) _____ t_3
SEQUENTIAL PULSE WIDTH (SPW) _____ t_4
QUIESCENT (LISTENING) PERIOD (QP) _____ t_5

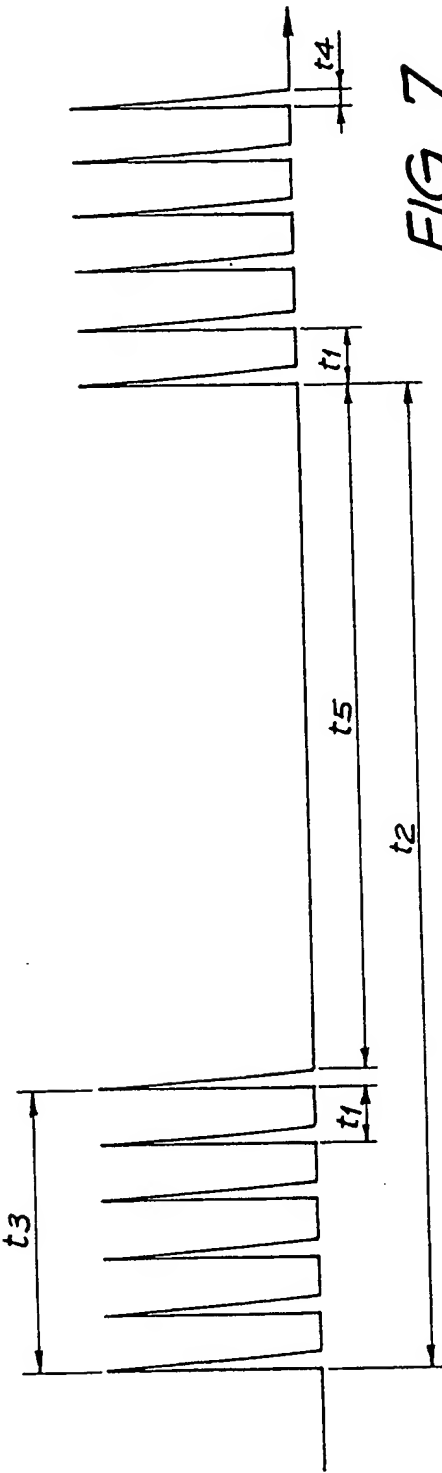


FIG. 7

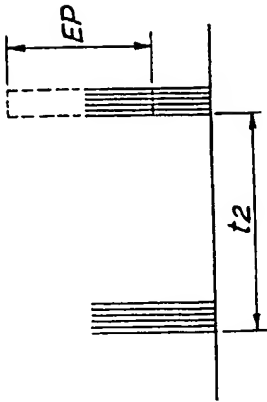


FIG. 7A

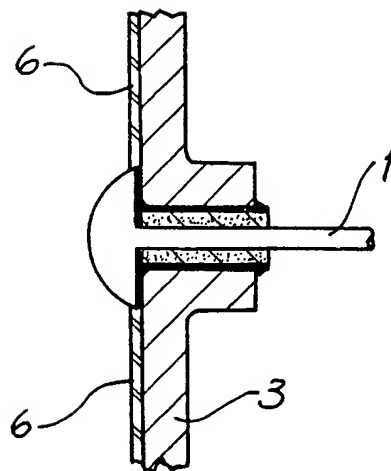


FIG. 9A

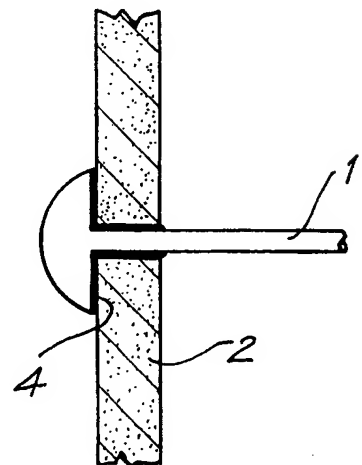


FIG. 9B

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00609

| A. CLASSIFICATION OF SUBJECT MATTER | | |
|--|--|---|
| Int Cl ⁶ A61N 1/36 | | |
| According to International Patent Classification (IPC) or to both national classification and IPC | | |
| B. FIELDS SEARCHED | | |
| Minimum documentation searched (classification system followed by classification symbols) IPC: A61N 1/- | | |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU :IPC as above | | |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT WPAT keywords: APICAL, APEX, PACEMAKER | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| P, X | US, 5772689, (KROLL) 30 June 1998 | 1 to 8, 10, 13, 15, 15 |
| X | WO 9408657 (GRAY) | 1 to 15, 15 |
| X | US 4686987 (SALO et al) 18 August 1987 | 1 to 8, 13 and 15 |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex | | |
| <p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> | | |
| Date of the actual completion of the international search 25 September 1998 | | Date of mailing of the international search report - 2 OCT 1998 |
| Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929 | | Authorized officer J.W. THOMSON Telephone No.: (02) 6283 2168 |

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00609

| C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|--|-----------------------|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | US 4313442 (KNUDSON et al) 2 February 1982 | 1 to 8, 13 and 15 |
| X | US 4289134 (BERNSTENIN) 15 September 1981 | 1 to 8, 13 and 15 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.
PCT/AU 98/00609

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | | | Patent Family Member | | | |
|--|---------|----|----------|----------------------|---------|----|---------|
| WO | 9408657 | AU | 53310/95 | US | 5674259 | US | 5792208 |
| | | AU | 17568/92 | | | | |
| WO | 9402201 | EP | 650381 | | | | |
| EP | 494487 | AU | 88880/91 | CA | 2046520 | JP | 6070989 |
| | | US | 5179949 | | | | |
| WO | 9010471 | US | 5103821 | | | | |
| US | 4686987 | US | 5190035 | | | | |
| END OF ANNEX | | | | | | | |

THIS PAGE BLANK (USPTO)